Abbott

ReVolt Against the Ordinary

Volt™ PFA System

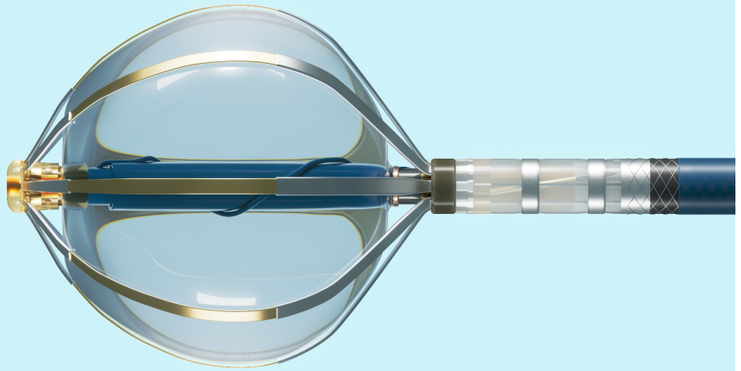
Reengineering PFA with the fewest applications[1] and total control

Volt™ PFA System simplifies therapy delivery, minimizing procedural burden so you can treat more patients with ease and precision[1*].

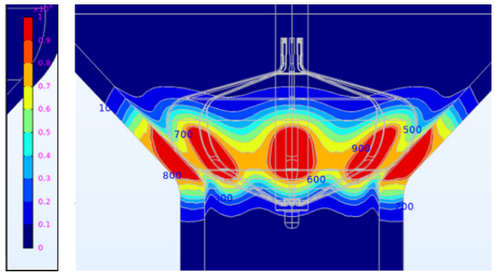
Volt™ PFA System

Volt™ PFA Catheter, Sensor Enabled™
Current™ PFA Generator
Agilis™ NxT Steerable Introducer, Dual-Reach™

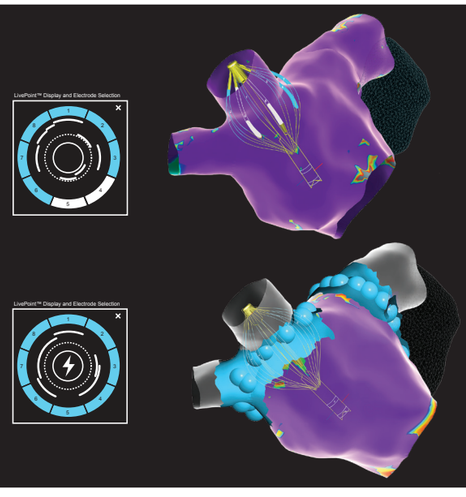
Simplicity by design



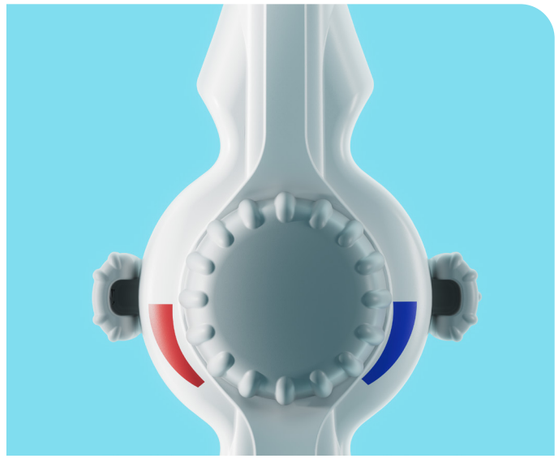
Delivers targeted lesion sets where it matters with an 8-spline balloon-in-basket design that conforms to anatomy and creates a wide-band lesion[2] for fewer repositions



Gain real-time procedural insight with elegant impedance-based contact visualization through AutoMark and eField integration for precise lesion tracking[3,4]



Three handling options for optimal positioning



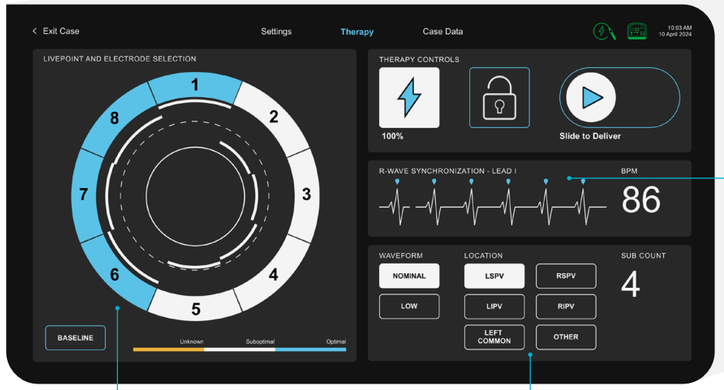
Bi-directional catheter handling

Bi-directional steering with Agilis™ NxT Steerable Introducer, Dual-Reach™, the leading choice globally for precision and control

Over-the-wire

Ensures ease of use and adaptability with an intuitive generator – designed for now and the future

Control at your fingertips



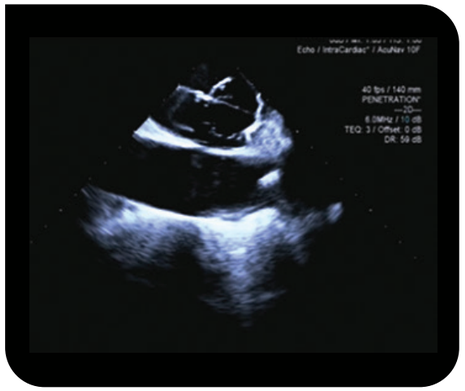
Prevent ventricular arrhythmia induction with R-Wave gated bipolar, biphasic waveforms

Make contact informed therapy applications with LivePoint™ Display

Customize therapy by tapping on/off electrodes to select those for delivery

Monitor applications by location, even in standalone mode

Current™ PFA Generator's waveforms are designed to minimize microbubbles[5] and patient movement for stability during energy delivery[2]



The only standalone generator with an integrated tissue contact display – empowering contact-guided energy applications, with or without a mapping system[4]

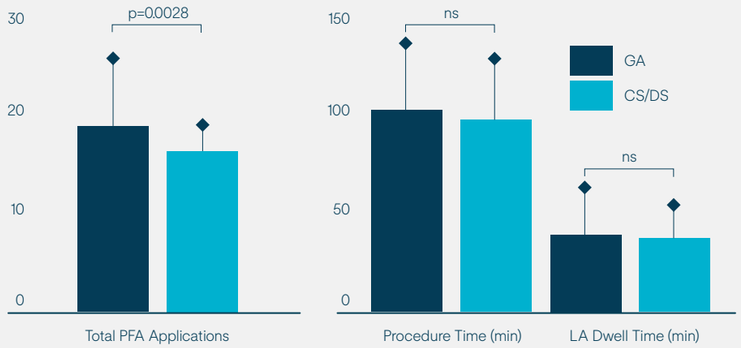
Features distal and proximal magnetic sensors for seamless EnSite™ X EP System integration – designed for now and the future

Eliminates the need for general anesthesia through light sedation compatibility[6], allowing for use with or without propofol

CE Mark Sub-Analysis

PVI with Volt™ PFA Catheter, Sensor Enabled™ in subjects under deep or conscious sedation (CS/DS) does not significantly impact safety or acute outcomes compared to procedures with general anesthesia (GA)[6].

Procedure characteristics



Acute effectiveness

98.9%

GA Subjects (90**/91)

98.2%

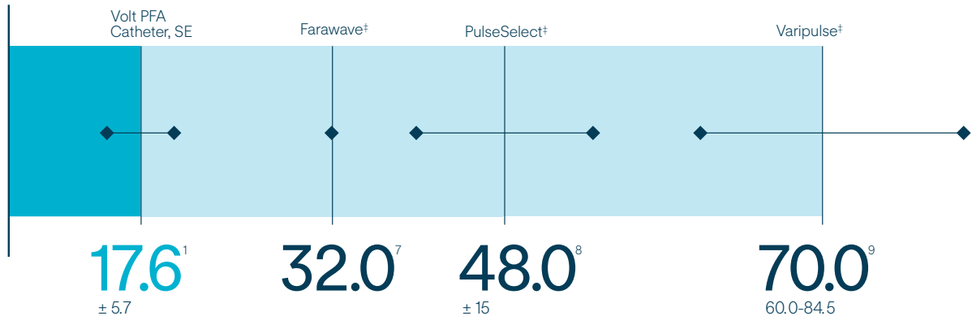
CS/DS Subjects (54†/55)

Unmatched performance with minimal applications

The lowest number of applications of any PFA tool[1] minimizing catheter repositions and increasing procedural efficiency[1]

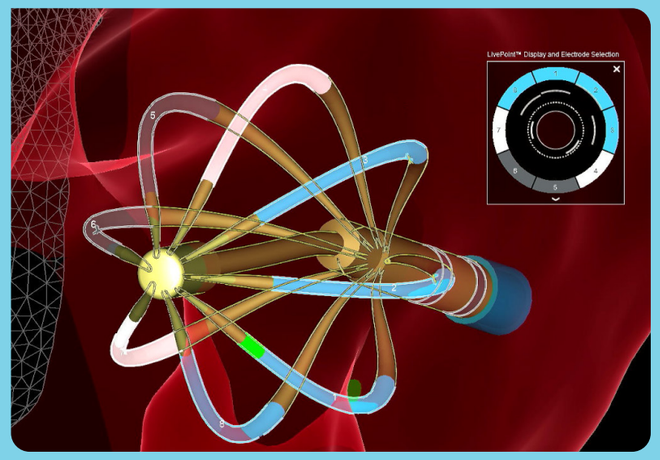
2 **Create PVI with as few as two applications per vein**[1]

Applications per patient***

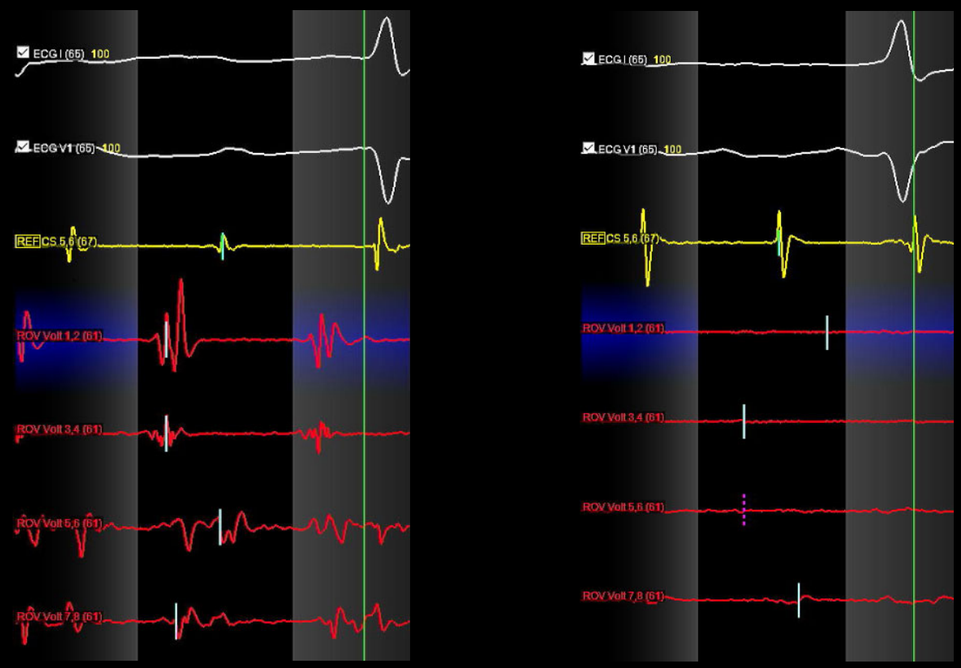


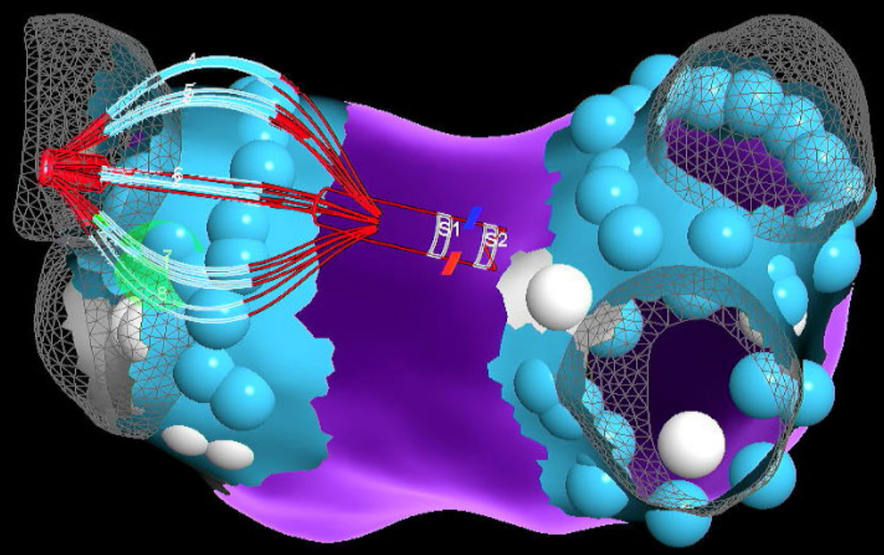
Based on published data from multicenter experience and separate studies, which may involve different patient populations and other variables. Not a head-to-head comparison. Data presented for informational purposes only.

Customize therapy for anatomic and patient variation by selectively delivering energy from electrodes in good contact



Enables a single-catheter workflow for mapping, pacing, and ablating, minimizing catheter exchanges





Treat more patients safely

CE Mark 6-month results[10]

Data from the Volt CE Mark study demonstrates that PVI with the Volt™ PFA System is both safe and effective for treating PAF and PsAF over a 6-month follow-up period.[10]

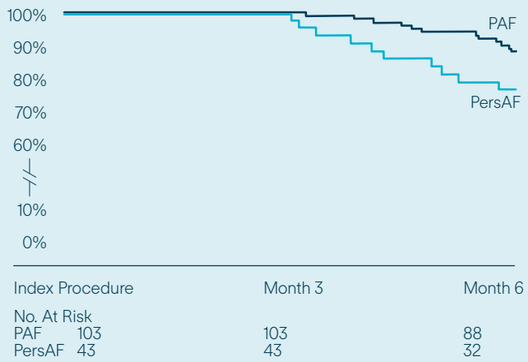
Effectiveness

88.2% of PAF

76.7% of PsAF

subjects free from documented AF/AFL/AT recurrence at 6-months.

6-month effectiveness



Repeat ablation and durably isolated PVs

1 in 20 The repeat ablation rate in the CE Mark cohort was only 1 in 20 patients (4.8%, n=7/146)

93.3% In repeat ablations after the blanking period, 93.3% of veins were durably isolated

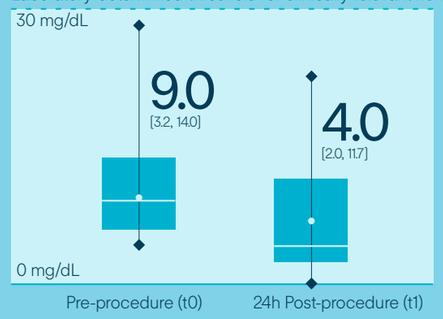
Primary safety endpoint[10]

0% of subjects reporting hemolysis, acute kidney injury, phrenic nerve injury

2.7% of subjects experienced a primary safety endpoint event

Reduces hemolysis[11,12] by directly targeting tissue, avoiding the blood pool, and removing the need for additional fluid[11]

Laboratory-determined threshold for clinically relevant hemolysis[12]



Plasma Free Hemoglobin (mg/dL) n=16 patients

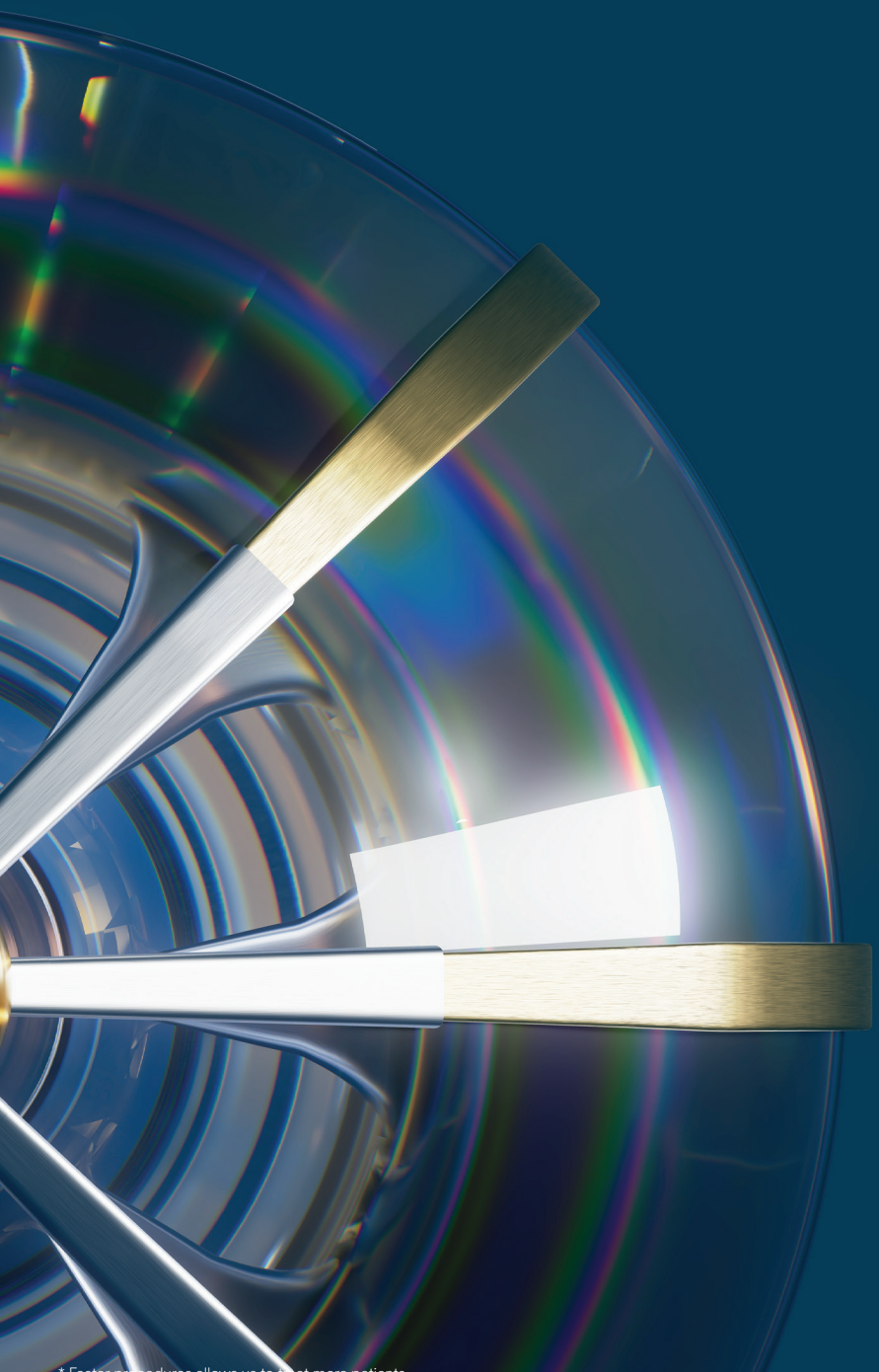
No periprocedural hydration protocol performed

Median applications per patient: 13.9 [8.0-26.0]

0%

Hemolysis or kidney injury reported[1]

ReVolt Against the Ordinary with the PFA system engineered for extraordinary performance



* Faster procedures allows us to treat more patients.
** 1 vein was not isolated after max therapy applications.
*** In listed CE Mark or IDE trials for achievement of PVI.
† 4 veins in 1 subject did not have assessment after 20 min wait period.

1. Tilz, R.R. (2025, January 17) Acute results demonstrate safety and effectiveness of balloon-based pulsed field ablation system for de novo PVI in PAF and PersAF [Late Breaking Presentation]. AF Symposium 2025, Boston MA, USA.
2. Data on file 90985059.
3. Data on file 91057904.
4. Data on file 91104530.
5. Data on file 90985036.
6. Acute safety and procedural characteristics of conscious and deep sedation to general anesthesia workflows with novel balloon-based PFA system (Oral presentation and abstract by Roland Tilz, EHRA 2025).
7. Reddy VY, Gerstenfeld EP, Natale A, et al. Pulsed Field or Conventional Thermal Ablation for Paroxysmal Atrial Fibrillation. NEngl J Med. 2023;389:1660-71. doi:10.1056/NEJMoa2307291.
8. Verma A, Haines DE, Boersma LV, et al. Pulsed Field Ablation for the Treatment of Atrial Fibrillation: PULSED AF Pivotal Trial. Circulation. 2023;151(14):1433-1445. doi:10.1161/CIRCULATIONAHA.123.063988.
9. Reddy VY, Calkins H, Mansour M, et al. Pulsed Field Ablation to Treat Paroxysmal Atrial Fibrillation: Safety and Effectiveness in the AdmIRE Pivotal Trial. Circulation. 2024;151(0). doi:10.1161/CIRCULATIONAHA.124.070333.
10. Late Breaker presentation at EHRA 2025. Safety and Effectiveness of balloon-based PFA system for de novo PVI to treat PAF and PersAF: 6-Month Results of the Volt CE Mark Study (Tilz et al).
11. Marcon L, Della Rocca DG, Vetta G, et al. Hemolysis Biomarkers After Pulmonary Vein Isolation via a Balloon-In-Basket PFA Catheter. Circulation. Online Version of Record before inclusion in an issue. doi:10.1161/CIRCULATIONAHA.124.070333.
12. Overmann JA, Marques M, Lafean C, Pipenhagen C, Moon BL, Verma A. Hemolysis Profile of a Novel Balloon-Filled Basket Pulsed Field Ablation Catheter. Poster presented at: AF Symposium 2025; 2025 Jan 15-17; Boston, MA.

Rx Only. Brief Summary: Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precautions, potential adverse events, and directions for use.

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